K083690

510(k) Summary for the FemVue™ Catheter System

Date of Summary:	December 10, 2008 (Supplement 001: May 7, 2009)
510(k) Submitter and Primary Contact:	Marc Finch Vice President, Regulatory and Clinical Affairs Femasys Inc. 5000 Research Court Suite 100 Suwanee, GA 30024 Tel: 770-500-3910 Fax: 770-500-3980 mfinch@femasys.com
Device Common Name:	Hysterosalpingography or Hysterosonography Catheter
FDA Device Classification Name:	Uterine Manipulator/Injector Cannula
Product Code:	LKF
Classification Regulation:	Unassigned
Device Class:	Unclassified, Pre-Amendment 510(k) Submission
Panel:	Obstetrics/Gynecology
Indication for Use:	Intended for the delivery of contrast media during hysterosalpingography (HSG) and saline infusion hysterosonography (SIS) for the evaluation of the fallopian tube(s) selectively and/or the uterus. The following are some clinical indications: suspected polyps, fibroids, adhesions, or endometrial thickening, and/or the selective evaluation of fallopian tube patency.
Device Description:	The FemVue Catheter System ("FCS") is comprised of two components: a Sheath and a latex free balloon Catheter. The Sheath is used to deliver the Catheter into the uterus.

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Substantial Equivalence:

Primary substantial equivalence focuses on equivalent device type, indication for use, principle of operation, and device description of the FCS compared to the Ackrad H/S Catheter Set and the AngioTech/MD Tech PBN Fallopian Tube Catheter System. The FCS also shares substantially equivalent key features with the Ackrad IUI Set for Intrauterine Insemination, including similar principles of operation for device placement, device description, safety features, and laboratory bench verification. Finally, the FCS has a substantially equivalent indication for use, placement location, and principle of operation for evaluation of the fallopian tubes, as compared to the Stargate Falloposcopy Catheter and Trifurcated Irrigation Tubing.

Summary of Testing:

The FCS was tested in compliance with the cytotoxicity, irritation, and sensitization biocompatibility methods of ISO 10993.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2009

Mr. Marc Finch
Vice President of Regulatory and Clinical Affairs
Femasys, Inc.
5000 Research Court, Suite 100
SUWANEE GA 30024

Re: K083690
Trade Name: FemVue™ Catheter System
Regulatory Class: Unclassified
Product Code: LKF
Dated: June 5, 2009
Received: June 9, 2009

Dear Mr. Finch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083690

Device Name: FemVue™ Catheter System

Indications for Use:

The FemVue™ Catheter System is intended for the delivery of contrast media during hysterosalpingogram (HSG) and saline infusion hysterosonography (SIS) for the evaluation of the fallopian tube(s) selectively and/or the uterus. The following are some clinical indications: suspected polyps, fibroids, adhesions, or endometrial thickening, and/or the selective evaluation of fallopian tube patency.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K083690